

REMARKS

In the Office Communication, dated March 24, 2004, in the above-referenced application the Examiner stated that all pending claims 1-16 were rejected. The Examiner first indicated that the current application appears to be a continuation-in-part as opposed to a continuation application and requested the Applicants to change the specification to reflect this. The Examiner next rejected claims 1-16 under 35 U.S.C. 103(a) as being unpatentable over Hernandez, *et al.*, U.S. Patent No. 6,235,795, in view of Granja, *et al.*, U.S. Patent No. 5,663,156. Lastly, the Examiner rejected claims 1-16 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,596,776.

The Applicants have carefully reviewed the Examiner's rejections, and the reasons therefore, and the prior art cited. In response, the Applicants have amended the specification to incorporate the ranges of aliphatic alcohols disclosed in co-pending Application No. 10/133,986. Co-pending Application No. 10/133,986 had been previously incorporated by reference; consequently, this amendment does not constitute "new matter". This amendment further addresses the issue of the application appearing to be a continuation-in-part application. The application by this amendment is correctly a continuation application. The Applicants are also filing concurrently herewith (1) a terminal disclaimer thereby traversing the provisional double patenting rejection of claims 1-16. Upon entry of this Response claims 1-16 are believed to be in condition for allowance. No new matter is added by this response.

1. Rejection of claims 1-16 under 35 U.S.C. § 103(a):

The Examiner has rejected claims 1-16 under 35 U.S.C. § 103(a) as being unpatentable over Hernandez, *et al.*, U.S. 6,235,795, in view of Granja, *et al.*, U.S. 6,235,795. The Examiner contends that Hernandez, *et al.*, discloses "mixtures of higher primary alcohols made from beeswax generically overlapping applicants' useful in treating ulcers and as anti-inflammatory agents as well as their production by extraction." The examiner goes on to state that Hernandez, *et al.*, "differs from the instant invention in that micronizing and use in treating cholesterol and inflammatory disorders is not disclosed. Gamble, *et al.*, for similar mixtures of alcohols, disclose treating inflammatory and cholesterol disorders as well as ulcers. Micronization is a standard pharmaceutical practice." The Examiner contends that it "would have been *prima facie* obvious at the time the invention was made to one of ordinary skill in the art to start with the teaching of the cited references, to make applicants'

compositions and to expect them to be useful in treating cholesterol and inflammatory disorders.”

Applicants respectfully traverse the Examiner’s rejection of claims 1-16. Applicants note that Hernandez, *et al.*, teaches a method for obtaining an isolated alcohol mixture of a certain composition of long chain alcohols that first involves saponification and extraction with a solvent, followed by successive recrystallizations in order to purify the alcohol mixture. These methods result in a mixture of C-20 to C-34 alcohols of a particular compositional profile.

In contrast, the present invention as embodied in claims as now amended teach a mixture of C-20 to C-34 alcohols having a much different compositional profile than that taught by Hernandez, *et al.* This is a direct consequence of the different methods employed by that of Hernandez, *et al.* Hernandez, *et al.*, thus results in the differing compositional profile of the final products. Use of the method taught by Applicants results in a different compositional profile of C-20 to C-34 alcohols. For example, Applicants disclose a range of tetracosanol of 12 to 30%, while Hernandez, *et al.* discloses tetracosanol of 9 to 15%; Applicants disclose 1-hexacosanol to be 13-30%, while Hernandez, *et al.* is 12-18%; Applicants disclose 1-octacosanol to be 12 to 25%, while Hernandez, *et al.* is 13 to 20%; Applicants disclose triacontanol to be 20-40%, while Hernandez, *et al.* is 20-30%; Applicants disclose 1-dotriacontanol to be 5 to 15%, while Hernandez, *et al.* is 13 to 21%; and finally, Applicants disclose 1-tetratriacontanol to be 0 to 5%, while Hernandez, *et al.* is 1.5 to 3.5%.

The Examiner has combined the rejection over Hernandez, *et al.*, with that of Granja, *et al.*, and apparently Gamble, *et al.* However, Applicants respectfully submit that the current application is a continuation of Gamble, *et al.*, and thus it is improper to cite Gamble, *et al.*, furthermore, the mixture of alcohols present in the compositions defined by claims 1-16 are obtained from different sources, prepared by methods different than the methods of the cited references, and differ in multiple ways in compositional profile from that of the cited references. There is no teaching or suggestion in any of the cited references of compositions obtained from natural starting materials having a unique compositional profile which is the same as or equivalent to that disclosed in the present invention.

Applicants accordingly submit that it would not have been obvious to one of skill in the art at the time the invention was made to produce a product mixture with a unique compositional profile as defined by amended claims 1-16. Applicants therefore respectfully

request that the Examiner to withdraw his rejection of claims 1-16 in view of the foregoing arguments.

2. Non-statutory Double Patenting Rejection of Claims 1-16:

The Examiner made a provisional rejection of claims 1-16 as being unpatentable over the claims of US Patent No. 6,596,776. By way of response, Applicants have provided, appended to this Response, a terminal disclaimer that conforms with the requirements of 37 C.F.R. 1.321 and the requisite fee. Accordingly, Applicants respectfully request withdrawal of this rejection.

CONCLUSIONS

All of the outstanding rejections having been addressed, all pending claims are believed to be in condition for allowance, and such action is respectfully requested.

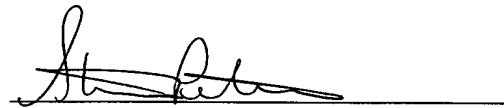
A terminal disclaimer is included with this response, together with the appropriate fees. The Examiner is authorized to charge any additional fees associated with the filing of this Amendment and the new claims presented herein to Deposit Account No. 50-1123

The Examiner is asked to kindly contact the undersigned by telephone should any outstanding issues remain.

Respectfully submitted,

9/21/04

Dated


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